510(K) SUMMARY

JAN - 9 2009

BIRTHTRACK SYSTEM

510(k) Number K082704

Applicant's Name:

Barnev Ltd.
8 Hamelacha St.
Netanya 42504
Israel
Tel: +972-9-8923130
Fax: +972-9-8923131
e-mail:info@barnev.com
www.barnev.com

Contact Person:

Ahava Stein, Regulatory Consultant
A. Stein – Regulatory Affairs Consulting
20 Hata'as St.
Kfar Saba 44425
Israel
Tel. + 972-9-7670002
Fax. +972-9-7668534
e-mail: ahava@asteinrac.com

Date Prepared: March 2008

Trade Name: **BirthTrack™** Continuous Labor Monitoring (CLM) System

Classification Name: **NPB**

Classification: Class II medical Device

Predicate Device: The BirthTrack System is comparable to the following predicate devices:

- The system evaluated is software version 2 of the previously cleared BirthTrack (K080672) manufactured by Barnev. It is enhanced with a new User Interface and a new algorithm.

Device Description: Barnev's BirthTrack system uses ultrasound technology to provide measurements of cervix dilatation and fetal head station. The BirthTrack Workflow and measurements cycle have not changed with this version and signals from disposable sensors located on the maternal cervix and fetal head provide objective and continuous cervical dilatation and fetal head station data, reducing the need for frequent vaginal examinations. However signal

analysis was enhanced with a new algorithm- a "side inclination" correction algorithm. The system's GUI was also enhanced introducing a graphic illustration of CD and HS as measured by the BirthTrack system

Intended Use / Indication for Use: The BirthTrack System is an ultrasound device intended to be used for monitoring the active phase of labor in women with term pregnancies, vertex presentation, and ruptured membranes. It is intended to be placed when cervical dilation is between 3 cm and 7 cm. The device continuously measures cervical dilation and fetal head station with ultrasound transducers attached to the maternal abdomen and cervix and to the fetal scalp. These measurements are displayed numerically and graphically as a function of time to show the progress of labor.

Performance Standards: The BirthTrack System complies with:

In addition, the device complies with the recognized standards: It also complies with ISO 11137, IEC-60601-1 and amendments, IEC 60601-1-2, IEC 60601-1-4, IEC 60601-2-37and AAMI/ANSI/ISO 10993-1.

Substantial Equivalence: Based on bench studies and clinical evaluation, we believe that the Birthtrack System is a low risk device. Moreover, the risks imposed by the Birthtrack system are lower or equal to these imposed by the predicate devices and standard medical practice. The performance of the Birthtrack system is substantially equivalent to the performance of its predicate device cited above and to these of manual procedures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2009

Barnev Ltd.
c/o Ms. Ahava Stein
A. Stein Regulatory Affairs Consulting
Beit Hapa 'amon (Box 124)
20 Hata 'as St.
44425 Kfar Saba
ISRAEL

Re: K082704
Trade/Device Name: BirthTrack™
Regulation Number: 21 CFR §884.2800
Regulation Name: Computerized labor monitoring system
Regulatory Class: II
Product Code: NPB
Dated: December 24, 2008
Received: January 2, 2009

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding os substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufactures, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry.suppot/index.html.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 1 – INDICATION FOR USE

510(K) Number (if known): K082704

Device Name: BirthTrack™

Indication for use: The BirthTrack System is an ultrasound device intended to be used for monitoring the active phase of labor in women with term pregnancies, vertex presentation, and ruptured membranes. It is intended to be placed when cervical dilation is between 3 cm and 7 cm. The device continuously measures cervical dilation and fetal head station with ultrasound transducers attached to the maternal abdomen and cervix and to the fetal scalp. These measurements are displayed numerically and graphically as a function of time to show the progress of labor.

Prescription Use ☒ OR Over the Counter Use__
(Per 21 CFR 801.109)

PLEASE DO MOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

510(K) Number K082704

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K082704